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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/430,735 10/29/99 EKWURIBE

N 4012-113-DIV

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INTELLECTUAL PROPERTY TECHNOLOGY LAW
P O BOX 14329
RESEARCH TRIANGLE PARK NC 27709

EXAMINER

HSU, G

ART UNIT

PAPER NUMBER

1627
DATE MAILED:

04/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/430,735

Applicant(s)
Ekwuribe et al.

Examiner
Grace Hsu, Ph.D.

Group Art Unit
1627



☒ Responsive to communication(s) filed on Jul 27, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 23-35, 46-61, 66, 67, and 70-72 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 23-35, 46-61, 66, 67, and 70-72 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is (703) 305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Keith MacMillan, Supervisory Examiner at Keith.Macmillan@uspto.gov or 703-308-4614. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. An Information Disclosure Statement was received on April 15, 1999 and entered as Paper No. 2 and a Preliminary Amendment filed on July 27, 1999 was entered as Paper No. 3.
2. Claims 23-35, 46-61, 66-67 and 70-72 are currently pending and claims 1-22, 36-45, 64-65 and 68-69 have been canceled in the instant application.
3. Claims 62-63 are withdrawn from consideration as the recited subject matter of those claims are not related to the subject matter of the pending claims subject to restriction in the instant application.

Election/Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 23-35 and 66-67, drawn to a method for activating a receptor into contact with an amphiphilic drug-oligomer conjugate, classified in class 424, subclass 130.1, in class 514, subclasses 2, 12, 558+ and in class 435, subclass 7.1.
 - II. Claim 46-52 and 70-71 drawn to a method for inducing analgesia in a subject, classified in class 514, subclass 2 and in class 435, subclass 7.1.
 - III. Claim 53-60 and 72, drawn to a method for altering the binding affinity of a peptide to a receptor, classified in class 530, subclass 329.
5. The inventions are distinct, each from the other, because of the following reasons:

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6. Groups I, II and III represent separate and distinct inventions. The aforementioned groups are different from each other, because those groups are drawn to different methods (which are directed to different purposes, use different materials, recite different method steps for the preparation of different product or lead to different final results). Therefore, Groups I, II and III have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

7. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species A** of the claimed invention:

<u>Species A</u>	<u>claim no.</u>	<u>The method of claim 23, wherein the receptor:</u>
(1)	claim 25	a G-protein coupled receptor
(2)	claim 26	an opioid receptor
(3)	claim 27	an opioid receptor, selected from the group consisting of δ , μ , and κ receptors.

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic.

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8. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species B** of the claimed invention:

<u>Species B</u>	<u>claim no.</u>	<u>The method of claim 23, wherein the hydrophobic moiety is selected from the group consisting of:</u>
(4)	claim 28	sugar and PEG ₁₋₇
(5)	claim 29	fatty acid, alkyl 1-26, cholesterol and adamantane

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic.

9. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species C** of the claimed invention:

<u>Species C</u>	<u>claim no.</u>	<u>The method of claim 23, wherein the therapeutic compound is:</u>
(6)	claim 30	a peptide having an added N-terminal residue selected from the group consisting of proline and alanine
(7)	claim 31	a peptide or protein
(8)	claim 32	a peptide or protein [see, elements as recited in claim 32]
(9)	claim 66	an opioid receptor agonist, antagonist or partial agonist/antagonist

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(10) claim 67 an enkephalin

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 23 is generic.

10. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species D** of the claimed invention:

<u>Species D</u>	<u>claim no.</u>	<u>The method of claim 23, wherein the hydrophobic moiety is coupled to the hydrophobic moiety by a :</u>
(11)	claim 34	a hydrolyzable bond
(12)	claim 35	a non-a hydrolyzable bond

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic.

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11. If applicants elect the invention of **Group II**, applicants are required to further elect from the following patentably distinct **Species E** of the claimed invention:

<u>Species E</u>	<u>claim no.</u>	<u>The method of claim 46, wherein the therapeutic compound is :</u>
(13)	claim 47	[met ⁵]enkephalin
(14)	claim 70	an opioid
(15)	claim 71	an enkephalin

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 is generic.

12. If applicants elect the invention of **Group III**, applicants are required to further elect from the following patentably distinct **Species F** of the claimed invention:

<u>Species F</u>	<u>claim no.</u>	<u>The method of claim 53, wherein the binding affinity is:</u>
(16)	claim 54	increased
(17)	claim 55	reduced

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

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Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 53 is generic.

13. Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

15. Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. These inventions are distinct for the reasons above and have acquired a separate status in the art because of their recognized divergent subject matter and/or shown by their different classifications. While some of the aforementioned groups are classified under an identical

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class/sub-class, the corresponding non-patent literature search remains unaffected. Each of the identified groups may require different searches. For example, methods and products groups require different searches. Therefore, restriction for examination purposes as indicated is proper.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Conclusion

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Grace C. Hsu, Ph.D., J.D. whose telephone number is (703) 308-7005. The Examiner may be reached during normal business hours, Monday through Friday from 8:30 am to 6:00 pm (EST). A message may be left on the Examiner's voice mail.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Keith Macmillan may be reached at (703) 308-4614. The fax number assigned to Group 1627 is (703) 305-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1627 receptionist whose telephone number is (703) 308-0196.

Grace C. Hsu, Ph.D.

April 9, 2000

**BENNETT CELSA
PRIMARY EXAMINER**





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